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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/147,947	03/24/1999	NOBUO TSURUOKA	001560-349	2472

21839 7590 05/29/2003

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EXAMINER

MOORE, WILLIAM W

ART UNIT	PAPER NUMBER
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1652

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DATE MAILED: 05/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.		Applicant(s)	
	09/147,947		TSURUOKA ET AL.	
	Examiner		Art Unit	
	William W. Moore		1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-9, 12, 14-16, 21-26, 31-33, 37-40, 44-47, 51 and 60-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5, 7-9, 14-16, 21-26, 31-33, 37-39, 44-46, 51 and 63 is/are allowed.
- 6) ☒ Claim(s) 6, 12, 40, 47 and 60-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION*Response to Amendment*

Applicant's Amendment F, Paper No. 24 filed March 6, 2003, has been entered and the cancellation of claims 27-30, 34-36, 42-43, 46-50, and 52-59, together with the amendments to claims 5, 6, 8, 9, 14-16, 22-26, 44-47 and 51 remove the bases for the objection of record of claims 6, 9, 27-30, 45-50 and 54-59 herein and also overcome the rejections of record of claims 8, 12, 27-30, 34-36, 40-44, 47-50, 52, 53 and 55-59 herein under the first paragraph of 35 U.S.C. § 112 for lack of enablement and lack of adequate written description, as well as the rejections of record of claims herein under the second paragraph of 35 U.S.C. § 112. Accordingly, claims 5, 7-9, 14-16, 21-26, 31-33, 37-39, 44-46, 51 and 63 are now indicated as allowable. Claims 6, 12, 40 and 47 previously rejected, and three of the newly-submitted claims 60-63 are, however, still subject to a rejection of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 12, 40 and 47 remain rejected, and new claims 60-62 are now rejected, essentially for reasons of record, under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim amendments of Paper No. 17 do not cancel any of claims 6, 12, 40 and 47 subject to the rejection of record, and the new claims 60-62 are now included in this rejection of record in view of their dependency from claim 6 because claim 6 recites, "is hybridizable with DNA having the nucleotide sequence of SEQ ID NO:3, under stringent conditions". Applicant's arguments filed March 6, 2003, have been fully considered but

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they are not persuasive. Applicant suggests, at page 7 of Paper No. 24, that the ability of artisans to design isocoding, but "hybridizable", nucleic acid sequences encoding a human amino neurotrypsin having the acid sequence set forth in SEQ ID NO:6, and to design "hybridizable" nucleic acid sequences that encode its constituent domains, enable the claimed subject matter. Claims 6, 12, 40 and 47 and new claims 60-62 are accordingly no longer rejected for lack of enablement herein under the first paragraph of the statute. Applicant then suggests at pages 7-8 of Paper No. 24 that the quotation of the USPTO's written description guidelines by a Federal Circuit panel, *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609, 1613 (Fed Cir. 2002), indicates that the disclosure of the specification is somehow sufficient to satisfy the written description requirement. This superficial treatment of the decision is counter to the reasoning therein:

"Although an actual reduction to practice, assuming one exists here, may demonstrate possession of an embodiment of an invention, it does not necessarily describe what the claimed invention is. In the context of this case, the disclosure of the way the invention was reduced to practice does not satisfy the more fundamental written description requirement set forth in the statute: "[t]he specification shall contain a written description" Enzo has merely disclosed that it obtained the sequences, but it has not identified them. We therefore conclude that Enzo's description of its reduction to practice, unaccompanied by any written disclosure of meaningful, distinguishing characteristics of the claimed invention, does not satisfy the written description requirement of § 112, ¶ 1."

Id. at 1615. No disclosure of the specification, explicit or inherent, shows that Applicant ever "obtained" any "hybridizable" DNAs encoding polypeptides beyond the neurotrypsin protease of SEQ ID NO:6, or its protease domain having the amino sequence from position 578 through position 822 of SEQ ID NO:6, or a kringle domain of the protease having the amino sequence from position 40 through position 112 of SEQ ID NO:6, or one of the four scavenger receptor cysteine-rich domains of the protease selected from the group consisting of an amino acid sequence from position 117 through position 217 of SEQ ID NO:6, an amino acid sequence from position 227 through position 327 of SEQ ID NO:6, an amino acid sequence from position 334 through position 433 of SEQ ID NO:6, and position 447 through position 547 of SEQ ID NO:6. There is no teaching of

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the design or preparation of hybridizable DNAs encoding divergent amino acid sequences, nor is there any evidence of the identification of hybridizable DNAs encoding divergent amino acid sequences from the recited human source. The artisan reading the instant specification cannot know where a "hybridizable", but not isocoding, DNA diverges in its coding capacity from the coding capacity of SEQ ID NO:3 herein.

The Court of Appeals for the Federal Circuit has determined that a claimed invention must be described with such "relevant identifying characteristic[s]" that the public could know that the inventor possessed the invention at the time an application for patent was filed, rather than by a mere "result that one might achieve if one had made that invention". *University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The specification's treatment of subject matters of claims 6, 12, 27-30, 34-36, 40-44, 47-50, 52, 53, and 55-59 is entirely prospective and skilled artisans in the relevant fields of molecular biology and mammalian genetics could neither predict the structure, or the coding capacities, of "hybridizable" DNAs that specify some other human polypeptide or its constituent domains. The rejection of record is sustained.

Citation of Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sonderegger, WO 98/49322, discloses, at page 3 as Formula I and pages 20-23 as the deduced amino acid sequence of SEQ ID NO:1, a human neurotrypsin amino acid sequence identical, from position 54 through position 875, to that of the human trypsin from position 1 through position 822 of SEQ ID NO:6 herein. This disclosure in an international patent application published under the PCT is inapplicable under 35 U.S.C. §§102(a) or (b) but the priority dates of the PCT publication are earlier than Applicant's priority dates for the instant application, would potentially make publication of a U.S. Patent based on Sonderegger's disclosure available under 35 U.S.C. §102(e).

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Conclusion

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

5 A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15 Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 703.308.0583. The examiner can normally be reached from 9:00AM-5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached at 703.308.3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703.308.4242 for regular communications and 703.308.0294 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0196.

William W. Moore
May 23, 2003


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